

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD,
INC., POLYPROPYLENE HERNIA
MESH PRODUCTS LIABILITY
LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
Stinson v. Davol, Inc., et al.
Case No. 2:18-cv-01022

DISCOVERY ORDER

Before the Court is Plaintiff's Motion to Compel Defendants' Complete Responses to Plaintiff's Second Set of Interrogatories (ECF No. 244). Defendants oppose Plaintiff's Motion. (ECF No. 250.) For the reasons that follow, Plaintiff's Motion is **DENIED**.

I. Background¹

Plaintiff's case is the third bellwether trial selected from thousands of cases in this multidistrict litigation ("MDL") against Defendants. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

The relevant facts here are that in 2015 Plaintiff underwent a right inguinal hernia repair

¹ For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case. (Dispositive Motions Order ("DMO") No. 7, ECF No. 225.) All docket citations are to the *Stinson* case, 2:18-cv-1022, unless otherwise noted.

with an Extra-Large PerFix Plug mesh, a product manufactured by Defendants. In 2017, Plaintiff underwent exploratory surgery to determine if he had a recurrent hernia or nerve entrapment because of chronic pain in his right groin area. The explanting surgeon, Dr. Radke, noted extensive scarring and found “a large ball approximately 2.5 cm in diameter of rolled up mesh next to the pubic tubercle.” (ECF No. 89-22 at PageID #1134.) Dr. Radke removed the mesh, which he described as “slow going and extremely difficult” because of the significant scarring. (*Id.*) Dr. Radke then repaired the hernia with another of Defendants’ products, Bard Marlex Mesh. (*Id.*) After the explant surgery, Plaintiff claims to have continuing chronic pain and other complications.

The crux of Plaintiff’s claims is that Defendants knew of certain risks presented by the PerFix Plug device but marketed and sold the device despite these risks and without appropriate warnings, causing Plaintiff’s injuries. Plaintiff alleges that the polypropylene in the PerFix Plug degrades after implantation, which enhances the chronic inflammatory response in the body. (ECF No. 124 at PageID #4826.) Plaintiff also claims that the inflammation and resulting fibrosis are exacerbated by the PerFix Plug’s shape, weight, and pore size. Plaintiff also claims that the PerFix Plug is susceptible to migration and has a high incidence of chronic pain. (*Id.*) According to Plaintiff, Defendants downplayed the rate and severity of complications caused by the PerFix Plug, even when faced with reports of negative outcomes, which created an unreasonable risk of significant and permanent harm to patients. (*Id.*) Plaintiff brings this action to recover for injuries sustained as a result of the implantation of the PerFix Plug, alleging that Defendants knew of the risks presented by the device but marketed and sold it despite these risks and without appropriate warnings.

II. Legal Standard

Rule 26(b)(1) of the Federal Rules of Civil Procedure governs the scope of discovery:

Unless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

Fed. R. Civ. P. 26(b)(1). "Determining the proper scope of discovery falls within the broad discretion of the trial court." *Gruenbaum v. Werner Enter., Inc.*, 270 F.R.D. 298, 302 (S.D. Ohio 2010) (citing *Lewis v. ACB Business Servs., Inc.*, 135 F.3d 389, 402 (6th Cir. 1998)). "An order denying further discovery will be grounds for reversal only if it was an abuse of discretion resulting in substantial prejudice." *Lewis*, 135 F.3d at 402 (internal quotation omitted). A court must limit discovery otherwise permitted by Rule 26 if it determines that:

- (i) The discovery sought is unreasonably cumulative or duplicative, or can be obtained from some other source that is more convenient, less burdensome, or less expensive;
- (ii) The party seeking discovery has had ample opportunity to obtain the information by discovery in the action; or
- (iii) The proposed discovery is outside the scope permitted by Rule 26(b)(1).

Fed. R. Civ. P. 26(b)(2)(C). "[D]iscovery, like all matters of procedure, has ultimate and necessary boundaries." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351–52 (1978) (internal citations omitted).

A party may serve interrogatories related to "any matter that may be inquired into under Rule 26(b)." Fed. R. Civ. P. 33(a)(2). If the answering party is a corporation, the interrogatories must be answered "by any officer or agent, who must furnish the information available to the party." Fed. R. Civ. P. 33(b)(1)(B). As it relates to business records:

- (d) If the answer to an interrogatory may be determined by examining, auditing, compiling, abstracting, or summarizing a party's business records (including electronically stored information, and if the burden of deriving or ascertaining the answer will be substantially the same for either party, the responding party may

answer by:

- (1) specifying the records that must be reviewed, in sufficient detail to enable the interrogating party to locate and identify them as readily as the responding party could; and
- (2) giving the interrogating party a reasonable opportunity to examine and audit the records and to make copies, compilations, abstracts, or summaries.

Fed. R. Civ. P. 33(d)(1)–(2). A party seeking discovery may file a motion to compel if a party fails to answer an interrogatory; “an evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond.” Fed. R. Civ. P. 37(a)(3)(B)(iii), (a)(4).

III. Analysis

At issue is a March 2011 “line fire” at Defendants’ Puerto Rico manufacturing facility. (ECF No. 221 at PageID #8846–48.)² The Court previously granted (ECF No. 236) Defendants’ Motion to Quash Plaintiff’s Notice to Take 30(b)(6) Deposition of Defendants’ Representative on Topics Relating to 2011 Line Fire and Request for Documents (ECF No. 221). In granting the motion, the Court noted that:

Plaintiff has had ample opportunity to obtain the information by discovery given the fact that the Complaint File was provided three times in 2019. Further, the line fire occurred in 2011; Plaintiff’s PerFix Plug was manufactured and implanted four years later. Defendants have offered to respond, under oath, that the inventory affected by the fire was disposed of and was not included in the device implanted in Plaintiff. All of this is in addition to the untimeliness issues previously addressed.

(ECF No. 236 at PageID #9313.) Defendants agreed to provide information through less burdensome means than a Rule 30(b)(6) deposition, such as responding to interrogatories. (ECF No. 221 at PageID #8857.) Plaintiff served, and Defendants responded to, a set of ten interrogatories. (ECF No. 244-2.) Plaintiff now seeks to compel supplemental responses to the

² For a more complete factual background, the reader is directed to the Court’s April 11, 2023 Discovery Order granting Defendants’ Motion to Quash Plaintiff’s Notice to Take 30(b)(6) Deposition of Defendants’ Representative on Topics Relating to 2011 Line Fire and Request for Documents (ECF No. 236).

interrogatories, “including detailed answers that identify the sources and support for all of Defendants’ conclusions, as well as whether any information related to these requests is being withheld under a claim of privilege,” or in the alternative, a Rule 30(b)(6) deposition to obtain the information. (ECF No. 244 at PageID #9389.)

Plaintiff claims that Defendants’ responses to the interrogatories lack specificity, fail to state the basis for their facts, and fail to state whether any responsive information has been withheld. (*Id.* at PageID #9390–9394.) Plaintiff “requested that Defendants state all facts and identify all documents and people that support their contention that the monofilament Marlex material used in Plaintiff’s PerFix Plug was not involved in or anywhere near the chiller at the time of the line fire.” (ECF No. 244 at PageID #9391.) In their responses to the interrogatories, Defendants stated that all materials exposed to the line fire were segregated and identified with a “QC reject” label and disposed of, and that at the time of the fire the material used to manufacture Plaintiff’s PerFix Plug several years later was in the warehouse, a “separate and distinct location” from the manufacturing area. (ECF No. 244-2 at PageID #9415.) The interrogatory responses, and the MMR and signed Inventory Disposal Authorization previously provided by Defendants, attest to the fact that all materials affected by the line fire were disposed of and therefore not used in the manufacture of Plaintiff’s PerFix Plug. (ECF No. 244-2 at PageID #9419–20; ECF No. 218-5 at PageID #8800.) The interrogatory responses also show that the material used in Plaintiff’s device was in a separate warehouse location during the fire and was not moved to the manufacturing area until October 2014, over three years after the June 2011 line fire. (ECF No. 244-2 at PageID #9416.)

Plaintiff also argues that he is entitled to further information regarding the line fire and the materials used in his PerFix Plug because the information pertains to “Defendants’ quality controls

in place at the time that Plaintiff's PerFix Plug was manufactured and its material components were received and kept by Defendants." (ECF No. 244 at PageID #9391.) According to Plaintiff, such information shows a "global issue related to a systemic failure of Defendants' quality systems." (*Id.* at PageID #9394.) However, as this Court has ruled previously:

Evidence showing that the Defendants were later in noncompliance is not only irrelevant and prejudicial for the reasons set forth above, but it is also propensity reasoning prohibited by Federal Rule of Evidence 404(a). In other words, it is designed to entice the jury to conclude that because the Defendants were regularly in noncompliance, they were in noncompliance [at the time in question].

(Case No. 18-cv-1509, Motions *in Limine* ("MIL") Order No. 11, ECF No. 415 at PageID #22188; *see also* Case No. 18-cv-1509, MIL Order No. 12, ECF No. 455 at PageID #23368; Case No. 18-cv-1320, MIL Order No. 36, ECF No. 312 at PageID #17408.) Plaintiff also does not explain how, other than as propensity reasoning, information regarding the line fire relates to "Defendants' quality controls in place at the time that Plaintiff's PerFix Plug was manufactured" over four years after the line fire. Plaintiff may not use evidence of the 2011 line fire to argue that, because of alleged quality management system ("QMS") issues at that time, there must have been problems with Defendants' QMS at the time Plaintiff's PerFix Plug was manufactured four years later. Evidence of alleged issues with Defendants' QMS in 2011 is not relevant to Plaintiff's claims regarding his PerFix Plug, which was manufactured and implanted in 2015.

Plaintiff's interrogatories are not limited to information regarding the line fire. Plaintiff also seeks information regarding:

- The use, destruction, or disposition of all portions of the batch of the Marlex monofilament, not just the portion used in the manufacture of Plaintiff's PerFix Plug;
- The receipt, inventory, tracking, storage, and production of all portions of the batch of the Marlex monofilament, not just the portion used in the manufacture of Plaintiff's PerFix Plug;

- Test results, data, and analysis regarding the portions of the batch of Marlex monofilament that were *not* exposed to the 2011 line fire; and
- The identification upon receipt of the batch of Marlex monofilament, including any data or testing defining the initial and ongoing stability/integrity assessment of the material throughout its manufacturing shelf life.

These interrogatories fall well outside the limited scope of the discovery regarding the line fire. Information about the monofilament generally, from its receipt by Defendants “throughout its manufacturing shelf life,” is not specific to the line fire and is information Plaintiff could have sought in general fact discovery. Defendants have provided lot history records regarding Plaintiff’s specific device, and the use, disposition, storage, tracking, analysis, and testing of *all* portions of the monofilament that were *not* affected by the line fire is similarly unrelated to the line fire and unrelated to the manufacture of Plaintiff’s device. Plaintiff’s claims that he “cannot track the material used in his PerFix Plug from receipt until manufacture” and cannot determine “what testing or stability assessments were performed on the monofilament Marlex material between receipt and manufacture of Plaintiff’s PerFix Plug” do not relate to the line fire. The Court agrees that Plaintiff has “attempt[ed] to shift the focus of his interrogatories to the broader issue of [Defendants’] manufacturing quality systems,” and the limited additional discovery was not intended to “allow Plaintiff to reopen discovery into general issues relating to [Defendants’] quality systems that could have been investigated years earlier.” (ECF No. 250 at PageID #9534.)

Plaintiff further argues that Defendants’ responses are insufficient because the verification was signed by “an individual who was not employed by Bard or Davol at the time of the events in question and who has no personal knowledge of any of the responses.” (ECF No. 244 at PageID #9394.) The verification was signed by Stephanie Kelly, the Associate General Counsel, Securities & Governance and Assistant Secretary, Corporate Law at Becton Dickinson and Company, who is an authorized agent of Defendants. (ECF No. 244-3 at PageID #9427.) Plaintiff

asks that Defendants “at least identify the individuals that provided Ms. Kelly with the facts contained in their responses as well as the documents which constitute the ‘corporate knowledge’ of Defendants.” (ECF No. 244 at PageID #9395.) Plaintiff also cites to Federal Rule of Evidence 602 to support his claim that the individual who signed the verification must have personal knowledge of the facts provided in response to the interrogatories. (*Id.*)

Plaintiff’s reliance on Rule 602 is misplaced. Rule 602 provides that “[a] witness may testify to a matter only if evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter.” Fed. R. Evid. 602. Plaintiff claims that because Ms. Kelly would be precluded from testifying to these facts at trial, she is not the proper person to sign the verification. (ECF No. 244 at PageID #9395.) Plaintiff cites to no authority to support his claim that the requirements of Rule 602 apply to interrogatories. Rule 33 of the Federal Rules of Civil Procedure provides that interrogatories directed to a corporation must be answered by “any officer or agent,” and does not restrict that to those with personal knowledge. Fed. R. Civ. P. 33(b)(1)(B); *see also United States v. 42 Jars, More or Less, Bee Royale Capsules*, 264 F.2d 666, 670 (3d Cir. 1959) (“[T]he agent who answers on behalf of the corporation does not need to have personal knowledge. The corporation’s attorney will do.”); *Petrosyan v. Maserati N. Am., Inc.*, No. CV 19-12425-DJC, 2020 WL 8458123, at *3 (D. Mass. Nov. 18, 2020) (“Indeed, the verification makes clear that Attorney Krueger does not have any personal information and that he verified the answers based on a review of records and other information obtained from MNA personnel. This practice is allowed by Rule 33.”); *AT&T Corp. v. Park I-10 Motors*, No. SA-13-CV-644-DAE, 2014 WL 12659767, at *2 (W.D. Tex. Apr. 28, 2014) (“An agent’s verification is not inappropriate simply because it is based on corporate records rather than personal knowledge.”). As Defendants point out, the verification “serve[s] to bind [Defendants] to the interrogatory responses, which was

the goal of this discovery as outlined by the Court's Order." (ECF No. 250 at PageID #9540 (citing ECF No. 236 at PageID #9313 ("Defendants have offered to respond, under oath, that the inventory affected by the fire was disposed of and was not included in the device implanted in Plaintiff."))).)

Although information need not be admissible in evidence to be discoverable, the matter must be relevant to Plaintiff's claims and proportional to the needs of the case. Fed. R. Civ. P. 26(b)(1). Plaintiff's broad interrogatories regarding the entire batch of Marlex monofilament and Defendants' QMS are not relevant to the matter at hand. The scope of this discovery was limited and for the purpose of determining whether the materials used in manufacturing Plaintiff's PerFix Plug were exposed to or damaged by the 2011 line fire. Plaintiff continues to argue that the signed documentation attesting that the materials affected by the line fire were disposed of is insufficient. (ECF Nos. 223, 244, 249.) As the Court pointed out in its prior Discovery Order:

Defendants have produced signed documentation that the materials affected by the line fire, which occurred four years prior to the manufacture of Plaintiff's PerFix Plug, were disposed of and were therefore not used in the manufacture of any devices. As the Court noted above, the Inventory Disposal Authorization indicated that the affected materials, including the 1.75 pounds of RM1100262, Lot 43-025999-1, were disposed of in 2011. (*Id.* at PageID #8800.) The Inventory Disposal Authorization was signed by a quality engineer and several management level employees. (*Id.*) Both the Inventory Disposal Authorization and the MRR contain an inventory of the affected materials, and the MRR also indicates that affected materials were identified with a "QC Reject label." (ECF No. 218-5 at PageID #8795.)

(ECF No. 236 at PageID #9312.) The signed Inventory Disposal Authorization and Defendants' answer to Interrogatory No. 1, verified under oath, demonstrate that the materials affected by the line fire were disposed of and therefore could not have been used in the manufacture of Plaintiff's PerFix Plug. (ECF No. 244-2 at PageID #94130–16.) Accordingly, Plaintiff's Motion (ECF No. 244) is **DENIED**.

IV. Conclusion

For the reasons set forth above, Plaintiff's Motion to Compel Defendants' Complete Responses to Plaintiff's Second Set of Interrogatories (ECF No. 244) is **DENIED**.

IT IS SO ORDERED.

6/8/2023

DATE

**EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE**